

### REMARKS

Upon entry of the foregoing amendments, claims 20 to 35 will be pending in the above-identified patent application. As detailed above, new claims 20 to 35 have been added in the place of canceled claims 1-19 to correct an error in which Applicants' claimed invention was mistakenly defined as a "method of *treating* a motoneuron disease." New claims 20 to 35 correctly define Applicants' invention as a "method of *preventing* a motoneuron disease," which is consistent with the claims as filed. A corresponding error occurred in related patent application Serial No. 10/644,150, wherein the "treating" claims were mistakenly replaced with the "preventing" claims. The error in application Serial No. 10/644,150 was also corrected by amendment submitted on June 1, 2005, such that the claims in application Serial No. 10/644,150 now correctly define a "method of *treating* a motoneuron disease."

The Action includes rejections under the Judicially Created Doctrine of Obviousness-Type Double Patenting as well as under 35 U.S.C. §§ 101 (Double Patenting), 102(b), and 103(a). In view of the foregoing amendments and the following remarks, reconsideration and withdrawal of the rejections are respectfully requested.

### Discussion of the Objections to the Claims

Claim 2 has been objected to because the term "treating" was recited twice. Applicants respectfully submit that, in view of the foregoing amendments, the objection is now moot.

### Discussion of the Rejection Under 35 U.S.C. § 101 (Double Patenting)

Claims 1 to 7 and 9 to 19 have been provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the "same invention" as that claimed in co-pending application Serial No. 10/644,150 ("the 150 application"). Applicants traverse respectfully this rejection as there is no overlapping subject matter between the present claims and the pending claims of the 150 application.

The claims of the present application are different from those of the 109 application. In this regard, the claims of the present application define a "method for *preventing* a motoneuron disease in a patient by increasing the survival and/or growth of motoneurons in said patient" (*see, e.g., claim 2*) (emphasis added). In contrast, the claims of the 150 application define a "method

for *treating*" a motoneuron disease (*see, e.g.*, claim 2 of the 150 application) (emphasis added). Indeed, although the claimed low molecular weight heparins may act to increase the survival and/or growth of motoneurons, *preventing* and *treating* a motoneuron disease are different actions. Accordingly, reconsideration and withdrawal of the provisional double patenting rejection are requested respectfully.

**Discussion of the Rejection Under the  
Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 1 to 7 and 9 to 19 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 34 of commonly-owned U.S. Patent No. 6,608,042. Applicants request that this rejection be deferred pending some identification of allowable subject matter, as it likely can be readily resolved (depending upon the subject matter ultimately allowed) through the filing of a suitable terminal disclaimer.

**Discussion of the Rejection Under 35 U.S.C. § 102(b)**

Claim 1 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lesma et al. (Journal of Neuroscience Research, 1996, 46, 565-571) ("the Lesma reference"). Although Applicants disagree that the Lesma reference anticipates claim 1, Applicants have nonetheless canceled claim 1, without prejudice to its presentation in a later-filed patent application, for the sole purpose of advancing prosecution of the present patent application. Accordingly, the rejection of claim 1 is now moot.

Claim 2 (new claim 20) has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by published PCT patent application No. WO 94/18988 to VonArnim ("the 988 application"). Applicants traverse respectfully this rejection as the 988 application does not disclose each and every element of Applicant's claimed invention as defined by claim 2.

Claim 2 (new claims 20) defines a "method for preventing a *motoneuron disease* in a patient in need thereof comprising administering to the patient a pharmaceutically effective amount of a low molecular weight heparin." Significantly, the 988 application does *not* teach or suggest prevention of a *motoneuron disease*.

In this regard, the 988 application teaches administering heparin for the treatment of *inflammatory diseases and immunological diseases* such as, for example, multiple sclerosis.

The Action, however, asserts that the 988 application anticipates claim 2 (new claim 20) because the disease “multiple sclerosis is within the scope of motoneuron diseases” (Action at 3). Such statement is demonstrably false as multiple sclerosis is *not* a motoneuron disease.

Multiple sclerosis (MS) is a demyelinating disease. A demyelinating disease is characterized by patchy destruction of myelin sheaths in the central nervous system (lesions) accompanied by an inflammatory response (*see, e.g.*, Harrison’s Principles of Internal Medicine, Twelfth Edition at pages 2038-2044 (1991); Exhibit A). While the cause of MS is not known with certainty, it is suspected that autoimmunity is likely implicated and, accordingly, MS is often referred to as an *autoimmune or an immunological disease* (*id.* at 2038). In further support, attached hereto as Exhibit B is a 1998 publication entitled “Understanding Autoimmune Diseases,” NIH Publication No. 98-4273 (“the NIH publication”). The NIH publication at page 3 clearly shows that multiple sclerosis is an example of an autoimmune disease.

A motoneuron disease, in contrast, is a disease characterized by progressive degeneration of motor neurons, *i.e.*, neurons that control the behavior of muscles (*see, e.g.*, the GAPS Index Glossary attached hereto as Exhibit C). Indeed, one of ordinary skill in the art understands that a demyelinating disease (or autoimmune disease) and a motoneuron disease *are different*. For example, the Abstract of the 1996 publication entitled “Investigation of corticospinal dysfunction in multiple sclerosis and motoneuron diseases using motor evoked potentials” by Gomez-Fernandez et al. (Exhibit D) clearly evidences that the skilled artisan considers multiple sclerosis to be *separate* and, thus, not included in the same class as motoneuron disease:

[t]he introduction of motor evoked potentials (MEP) into neurological practice has been very useful in the study of motor disorders, especially in patients with *motor neurone diseases (MND) and multiple sclerosis*

(emphasis added). Referring back to Exhibit C, “motor neurone disease” is synonymous with “motoneuron disease.”

The Action, however, appears to base its conclusion that MS is a motoneuron disease on a statement from an internet publication by the American Speech-Language-Hearing Association entitled “Amyotrophic Lateral Sclerosis” that appears to categorize MS as a “motor neuron disorder.” Applicants submit respectfully that, in view of the above evidence, the statement relied upon by the Action is, at best, suspect. Indeed, the medical literature classifies MS as a demyelinating disease and *not* a motoneuron disease. Thus, since multiple sclerosis is not a

motoneuron disease, the rejection for alleged anticipation in view of the 988 application is improper and should be withdrawn. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ.2d 1051, 1053 (Fed. Cir. 1987) (“[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”).

**Discussion of the Rejection Under 35 U.S.C. § 103(a)**

Claims 1 to 19 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the 988 application in combination with the American Speech-Language-Hearing Association publication entitled “Amyotrophic Lateral Sclerosis” (“the AMSLH publication”) and the Lesma reference. Applicants respectfully traverse this rejection.

Since, as discussed above, the 988 application does not teach or suggest a “method for preventing a *motoneuron disease* in a patient (but, rather, treatment of a demyelinating disease), even if the AMSLH and Lesma references disclosed the additional recitations in Applicants’ claims (for purposes of argument only), its combination with the AMSLH and Lesma references still would not render obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based upon the combination of the 988 patent with the AMSLH and Lesma references are respectfully requested.

Claims 1 to 19 have also been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,608,042 (“the 042 patent”). Applicants traverse this rejection respectfully.

The 042 patent was filed in the United States on March 26, 2001, and issued on August 19, 2003. The present patent application was filed on August 20, 2003 – one day after the 042 patent issued; however, the present application is a divisional patent application of U.S. application Serial No. 09/881,267 (“the 267 application”), filed on June 14, 2001 – after the filing date of the 042 patent. As acknowledged by the Action at page 8, the 042 patent is available as prior art under 35 U.S.C. § 102(e).

35 U.S.C. § 103(c) states that

[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, *shall not preclude patentability under this section where the subject matter and the claimed invention were,*

*at the time the invention was made, owned by the same person or*  
subject to an obligation of assignment to the same person

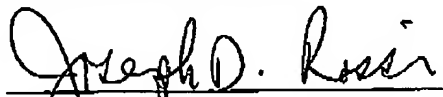
(emphasis added). Without commenting on the merits of the rejection under 35 U.S.C. § 103(a), Applicants submit that the subject matter of the 042 patent and the claimed invention were commonly owned by Aventis Pharma SA ("Aventis") or its predecessor in interest *at the time the present invention was made*. Since the subject matter of the 042 patent and the claimed invention were commonly owned by Aventis or its predecessor in interest at the time the present invention was made, the 042 patent is not available to preclude patentability under 35 U.S.C. § 103(a). Accordingly, Applicants submit respectfully that the rejection must be withdrawn in view of 35 U.S.C. § 103(c).

**Conclusion**

The foregoing is submitted as a full and complete response to the Action mailed on September 24, 2004, and the allowance of all claims is respectfully requested. If there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney at (908) 231-3410.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,



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